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Re: CPI® Ventak® PRx® AICD System
Docket No. 94E-0315

NOV - 3 1994

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,407,288, filed by Cardiac Pacemakers, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for CPI® Ventak® PRx® AICD System, the medical device claimed by the patent.

The total length of the review period for CPI® Ventak® PRx® AICD System is 1,306 days. Of this time, 398 days occurred during the testing phase and 908 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun:
November 21, 1990.

FDA has verified the applicant's claim that the date the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 21, 1990.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act:
December 23, 1991.

The applicant claims December 20, 1991 as the date the Premarket Approval Application (PMA) for CPI® Ventak® PRx® AICD System (PMA P910077) was initially submitted. However, FDA records indicate that PMA P910077 was submitted on December 23, 1991.

3. The date the application was approved: June 17, 1994.

FDA has verified the applicant's claim that PMA P910077 was approved on Jun 17, 1994.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Peter Forrest
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